ResMed

Mirage™ FX for Her

NASAL MASK

User Guide

English

Provided for your reference by
cpapXchange.com

Did you know?

Replacing your mask and supplies is one of the most important steps in maintaining effective therapy.

Replace when...

- The cushion is no longer clear and transparent.
- The cushion is cracked, torn or damaged in any way.
- The headgear is stretched and needs to be tightened more than when it was new.

What to do...

Consult your equipment provider to learn what replacement schedule may be available through your insurance policy.

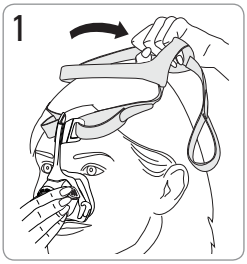
RESMED

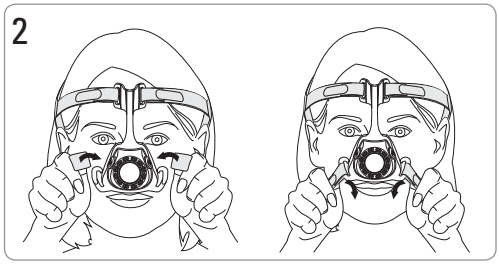
Mirage™ FX for Her

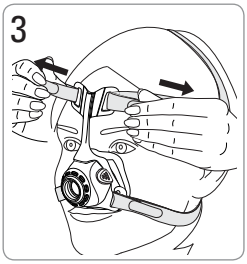
NASAL MASK

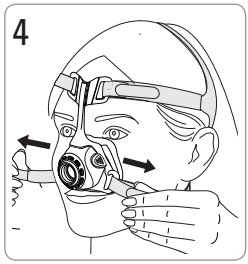
℞ Only

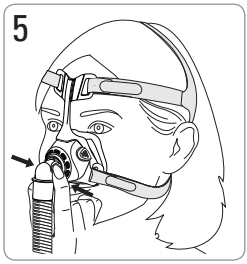
Fitting/Ajustement/Colocación/Colocação e ajuste

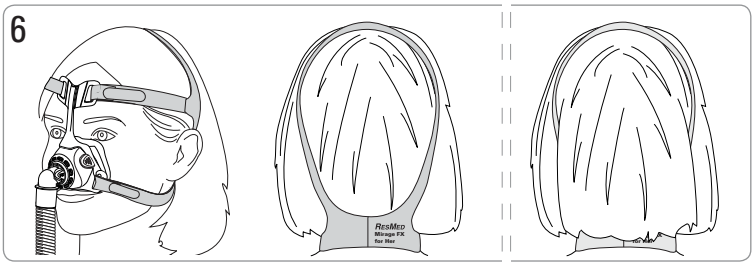




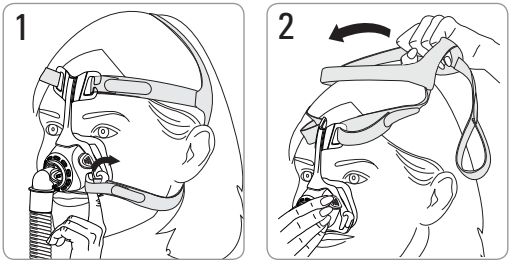




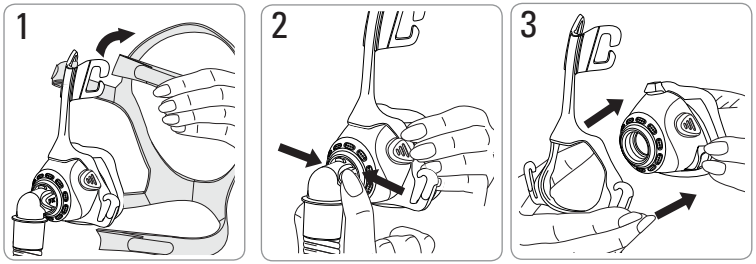




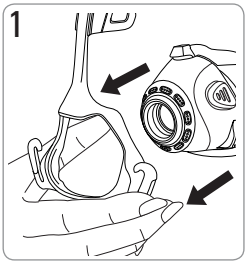
Removal/Retrait/Remoción/Remoção

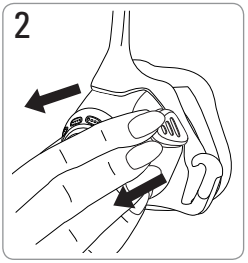


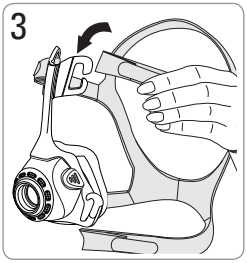
Disassembly/Démontage/Desmontaje/Desmontagem

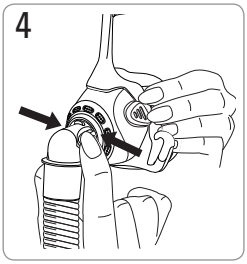


Reassembly/Remontage/Montaje/Remontagem

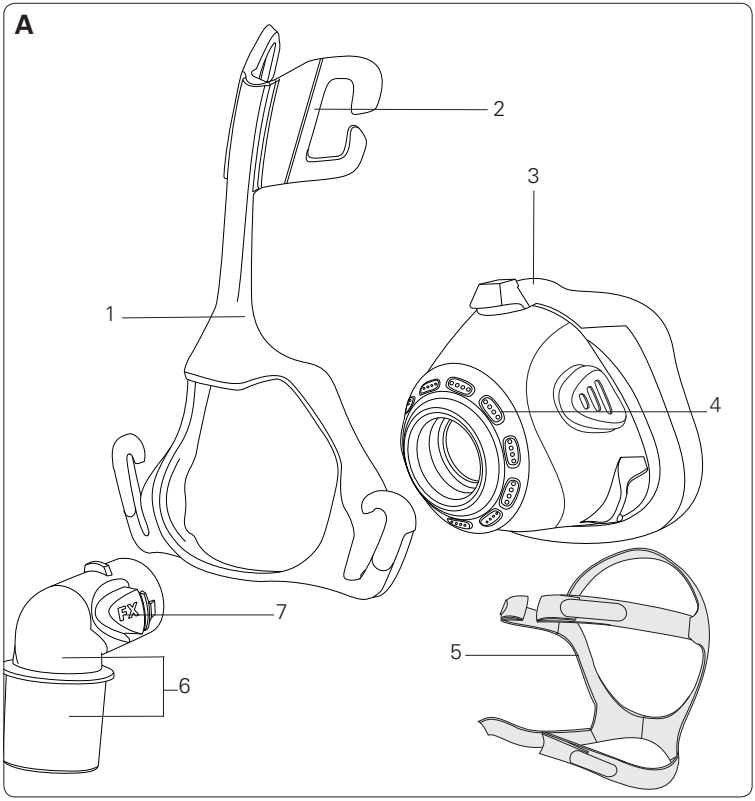


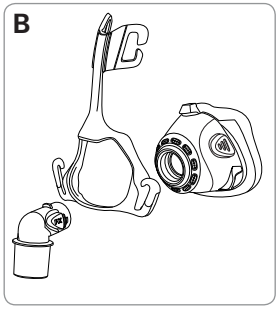






Mirage FX for Her





Mask components/Composants du masque/ Piezas de la mascarilla/Componentes da máscara

Item/ Article/ Artículo/ Item	Description/Description/Descripción/Descrição	Part number/ Code produit/ Número de pieza/ Número da peça
1	Mask frame/Entourage rigide/ Armazón de la mascarilla/Armação da máscara	—
2	Forehead support/Support frontal/ Apoyo para la frente/Suporte para a testa	—
3	Cushion/Bulle/Almohadilla/Almofada	62111 62136 (S)
4	Vent/Orifice de ventilation/Ventilación/ Respiradouro	—
5	Headgear/Harnais/Arnés/Arnês	62129
6	Elbow assembly/Ensemble coude/ Conjunto del codo/Conjunto do cotovelo	—
7	Elbow side tabs/Pattes d'attache latérales coude/ Lengüetas laterales del codo/ Abas laterais do cotovelo	—
A	Complete system/Système complet/ Sistema completo/Sistema completo	62128 62109 (S)
B	Frame system/Entourage complet/ Sistema de armazón/Sistema da armação	62112 62137 (S)

S: Small / Petit / Pequeño / Pequeno

Mirage™ FX for Her

NASAL MASK

Thank you for choosing the Mirage FX for Her. Please read the entire manual before use.

Intended use

The Mirage FX for Her channels airflow non-invasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device. The Mirage FX for Her is:

- to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

⚠ WARNING

- The vent holes must be kept clear.
- This mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air. **Explanation:** CPAP and bilevel devices are intended to be used with special masks (or connectors which have vent holes to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Remove all packaging before using the mask.

- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.

Using your mask

When using your mask with ResMed CPAP or bilevel devices that have mask setting options, refer to the Technical specifications section in this user guide for mask setting options.
For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on www.resmed.com on the **Products** page under **Service & Support**. If you do not have internet access, please contact your ResMed representative.
Note: *If you experience nasal dryness or irritation, using a humidifier is recommended.*

Fitting

The fitting illustrations section in this user guide show the sequence for obtaining the best fit and comfort when using your mask.

Fitting steps

Prior to fitting your mask, remove the elbow from the mask by pressing the side tabs. Connect the elbow to your device air tubing.

1. With both lower headgear straps released, hold the mask against your face and pull the headgear over your head.
2. Bringing the lower straps below your ears, loop the headgear into the lower hooks on the mask frame.
3. Unfasten the Velcro®, pull the upper headgear straps evenly until they are comfortable and reattach the Velcro. Do not overtighten.
4. Repeat step 3 with the lower headgear straps.
5. Attach the combined elbow assembly and air tubing to the mask by pressing the side-tabs and pushing into mask frame.
6. Your mask and headgear should be positioned as shown. Ensure the headgear label is facing outwards.

Removing the mask

Refer to the removal illustrations section in this user guide. To remove your mask, disconnect one of the lower headgear hooks and pull the mask and headgear up over your head.

Disassembly

Refer to the disassembly illustrations in this user guide.

	Disassembly steps
1.	Unhook the upper headgear straps from the mask frame, there is no need to undo the Velcro.
2.	Remove the combined elbow assembly and air tubing from the mask by pressing the side-tabs and pulling away from the mask frame. Remove the elbow assembly from the air tubing.
3.	Gently separate the cushion from the mask frame.

Reassembly

Refer to the reassembly illustrations in this user guide.

	Reassembly steps
1.	Ensure the cushion is oriented correctly by aligning the top cushion tab with the recess in the top of the mask.
2.	Gently pull the cushion through the front of the mask frame until the cushion locks securely into the mask frame. The tabs on either side of the cushion should be sitting against the mask frame. Ensure the cushion is not twisted or distorted.
3.	Attach the top headgear straps to the mask frame by looping onto each of the upper headgear hooks.
4.	Replace the elbow assembly into the air tubing and attach the combined elbow assembly and air tubing to the mask by pressing the side-tabs and pushing into the mask.

Cleaning your mask in the home

Your mask and headgear should only be gently handwashed.

Daily/After each use:

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approximately 86°F/30°C) water using mild soap.
- To optimize the mask seal, facial oils should be removed from the cushion after use.
- Use a soft bristle brush to clean the vent.
- Inspect each component and if required, repeat washing until visually clean.
- Rinse all components well with drinking quality water and allow to air dry out of direct sunlight.
- When all components are dry, reassemble according to the reassembly instructions.

Weekly:

- Handwash the headgear.

⚠ WARNING

Do not use aromatic-based solutions or scented oils (eg, eucalyptus or essential oils), bleach, alcohol or products that smell strongly (eg, citrus) to clean any of the mask components. Residual vapours from these solutions can be inhaled if not rinsed thoroughly. They may also damage the mask.

⚠ CAUTION

If any visible deterioration of a system component is apparent (cracking, crazing, tears etc), or, if after cleaning, any component remains unclean, the component should be discarded and replaced.

Reprocessing the mask between patients

This mask should be reprocessed when used between patients. Cleaning, disinfection and sterilization instructions are available from the ResMed website, www.resmed.com/masks/sterilization/americas. If you do not have internet access, please contact your ResMed representative.

Troubleshooting

Problem/possible cause	Solution
Mask is too noisy	
Vent is blocked or partially blocked.	If the vent requires cleaning, use a soft bristle brush.
Elbow incorrectly inserted.	Remove the elbow from the mask and then reassemble according to the instructions.
Mask leaks around the face	
Mask not positioned correctly.	Gently pull the cushion away from the face to reinflate. Reposition your mask according to the instructions.
Air leaking around the bridge of the nose	
Mask is not tightened correctly.	Tighten top headgear straps. Do not overtighten.
Air leaking around the sides of the nose	
Mask is not tightened correctly.	Tighten both upper and lower headgear straps. Do not overtighten. Turn off the CPAP or bilevel device and remove mask. Refit the mask according to the instructions. Ensure you position the cushion correctly on the face before pulling headgear over the head. Do not slide mask down the face during fitting as this may lead to folding or curling of the cushion.

The mask does not fit properly	
Mask is incorrectly assembled.	Disassemble the mask, then reassemble according to the instructions.
Cushion may be dirty.	Clean cushion according to the instructions.

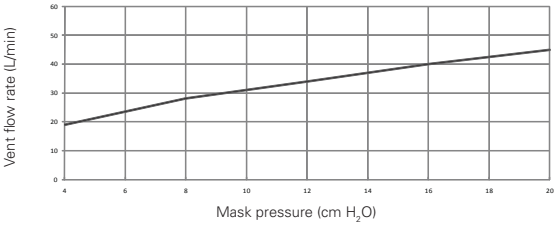
⚠ WARNING

- The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bilevel device. If used outside specification or if used with incompatible devices; the seal and comfort of the mask may not be effective; optimum therapy may not be achieved; and leak, or variation in the rate of leak may affect the CPAP or bilevel device function.
- Discontinue using this mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate. This warning applies to most types of CPAP devices.

Technical specifications

Pressure–flow curve

The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



Pressure (cm H_2O)	Flow (L/min)
4	19
8	28
12	34
16	40
20	45

Dead space information	Physical dead space is the empty volume of the mask to the end of the swivel. It is 93 mL.
Therapy pressure	4 to 20 cm H_2O
Resistance	Drop in pressure measured (nominal) at 50 L/min: 0.2 cm H_2O at 100 L/min: 1.0 cm H_2O
Environmental conditions	Operating temperature: +41°F to +104°F (+5°C to +40°C) Operating humidity: 15% to 95% non-condensing. Storage and transport: -4°F to +140°F (-20°C to +60°C) Storage and transport humidity: up to 95% non-condensing.
Gross dimensions	Mask fully assembled with elbow assembly – no headgear. 5.43" (H) x 3.38" (W) x 3.46 " (D) 138 mm (H) x 86 mm (W) x 88 mm (D)
Mask setting options	**For S9:** Select 'NASAL' **For other devices:** Select 'STANDARD', otherwise select 'VISTA' as the mask option.

Notes:

- *The mask system does not contain PVC, DEHP or phthalates.*
- *This product does not contain natural rubber latex.*

- *The manufacturer reserves the right to change these specifications without notice.*

Storage

Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.

Disposal

This mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Symbols

The following symbols may appear on your product or packaging.

⚠ Caution, consult accompanying documents; LOT Batch Code; REF Catalogue number; Temperature limitation; Humidity limitation; Does not contain natural rubber latex; Manufacturer; ⚠ Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device; Keep away from rain; This way up; Fragile, handle with care; EC REP European Authorized Representative; ℞ Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician.)

Limited warranty

ResMed Ltd (hereafter 'ResMed') warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) shall be free from defects in material and workmanship from the date of purchase for the period of 90 days or in the case of disposable masks the maximum use period.

This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use ResMed will repair or replace, at its option, the defective product or any of its components.

This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; and c) any damage or contamination due to cigarette, pipe, cigar or other smoke.

Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

Manufacturer:
ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia.
Distributed by:
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EC REP ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK.
See www.resmed.com for other ResMed locations worldwide.

Mirage FX for Her
Protected by patents: AU 785376, EP 1314445, EP 1582230, HK 1057714, JP 4354664, JP 4607913, US 6581594, US 6823865, US 7159587. Other patents pending.
Protected by design registrations: AU 336564, AU 336565, AU 336566, AU 336567, AU 336568, CN 201030631361.9, EU 1781709, NZ 414291, NZ 414683, NZ 414684, NZ 414685, NZ 414686. Others pending. Mirage is a trademark of ResMed Ltd and is registered in U.S. Patent and Trademark Office.

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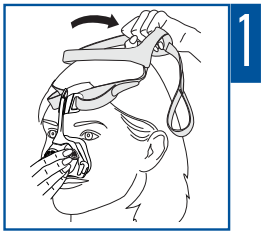

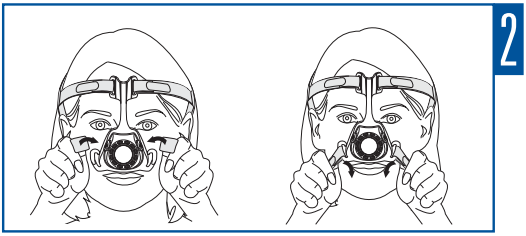

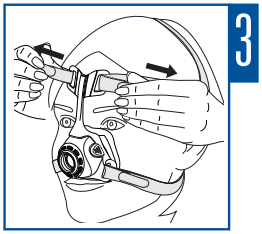

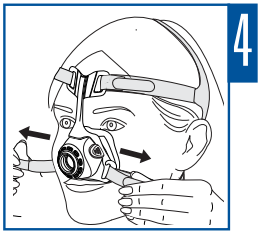

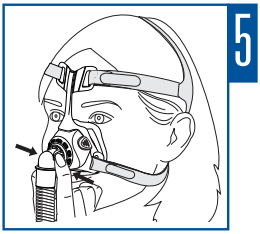

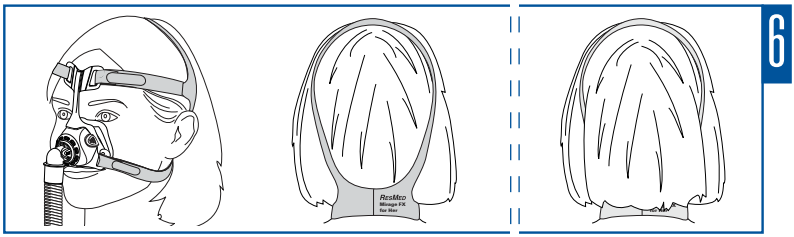

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